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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,189	09/21/2006	Alexei Shir	29770	5260

7590 12/27/2007
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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,189	Applicant(s) SHIR ET AL.	
	Examiner Terra C. Gibbs	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-98 is/are pending in the application.
- 4a) Of the above claim(s) 72-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>February 7, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's Election filed October 11, 2007.

Claims 72-98 are pending in the instant application.

Election/Restrictions

Applicant's election of Group II, namely claims 96-98, drawn to a method of killing a specific target cell and/or tissue comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising a double stranded RNA molecule associated with a targeting moiety capable of targeting to a specific cell and/or tissue type, in the reply filed on October 11, 2007 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

Claims 72-95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As discussed above, since Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election filed October 11, 2007 has been treated as an election **without** traverse.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 96-98 have been examined on the merits.

Information Disclosure Statement

The information disclosure statement filed February 2, 2007 is acknowledged. However, only the Abstracts of Reference #1 and Reference #25 have been considered on the merits since only the Abstract of the German Patent and only the Abstract of the Japanese reference, respectively were provided. The information disclosure submission is in compliance with the provisions of 37 CFR §1.97. Accordingly, the Examiner has considered the information disclosure statement filed February 2, 2007, and a signed copy is enclosed herewith.

Specification

The specification is objected to because the specification at pages 21, 27, and 47 contains embedded hyperlinks and/or other forms of browser-executable code that are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Furthermore, if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring a user to a commercial web site. Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of the information contained on these outside sites. The above are examples and are not intended to indicate that the Examiner has made an exhaustive review of the application. Applicant

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must delete the embedded hyperlink and/or other form(s) of browser-executable code in order for any response to this action to be considered fully responsive.

Drawings

The drawings filed on May 17, 2005 are acknowledged and have been accepted by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 96-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 96 recites, "A method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising a double stranded RNA molecule associated with a targeting moiety selected capable of targeting to the specific target cell and/or tissue". The word "selected" in line 4 of the claim seems to be unnecessary and its presence makes the wording of the claim grammatically incorrect. Appropriate correction is required. It is noted that claims 97 and 98 are included in this rejection because of their dependency therein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 96-98 are rejected under 35 U.S.C. 102(a) as being anticipated by Abounader et al. (The FASEB Journal, 2002 Jan;16(1):108-10. Epub 2001 Nov 29).

Claim 96 is drawn to a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising a double stranded RNA molecule associated with a targeting moiety capable of targeting to the specific target cell and/or tissue, thereby killing the specific target cell and/or tissue. Claims 97 and 98 depend on claim 96 and include all the limitations of claim 96 with the further limitations wherein said exposing the specific target cell and/or tissue to said composition-of-matter is effected by administering said composition-of-matter to a vertebrate subject bearing the specific target cell and/or tissue; and wherein said administering said composition-of-matter to said vertebrate subject is effected by administering said composition-of-matter to said subject systemically and/or to a central nervous system location of said vertebrate subject.

Abounader et al. disclose that the *in vivo* targeting of scatter factor/hepatocyte growth factor and c-met expression via U1snRNA/ribozymes inhibits glioma growth and angiogenesis and promotes apoptosis (see Abstract and Figure 1A). Specifically,

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Abounader et al. discloses that U1snRNA/ribozymes targeted to either scatter factor/hepatocyte growth factor or c-met expression, or both was i.v. injected into the tail vein of xenografted animals, scatter factor/hepatocyte growth factor and c-met expression was inhibited, and programmed cell death or apoptosis was increased in tumor tissue (see Figure 3 and Figure 4, for example).

Therefore, Abounader et al. anticipate claims 96-98.

Claims 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Czubayko et al. (Proc. Natl. Acad. Sci., 1996 Vol. 93:14753-14758).

Czubayko et al. disclose that melanoma angiogenesis and metastasis is modulated by a ribozyme targeted to the secreted growth factor pleiotrophin (see Abstract). Specifically, Czubayko et al. disclose that pleiotrophin specific ribozyme expression vectors were subcutaneously injected into nude mice, pleiotrophin expression was decreased, and apoptosis was increased in tumor tissues (see Figure 3 and page 14756, for example).

Therefore, Czubayko et al. anticipate claims 96-98.

Claims 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (Development, 1998 Vol. 125:1899-1907).

Zhao et al. disclose the selective disruption of neuregulin-1 function in vertebrate embryos using ribozyme-tRNA transgenes (see Abstract and Figure 1). Zhao et al. disclose that neuregulin-1 promotes muscle cell differentiation in the heart and neuronal

differentiation in the central nervous system (see Abstract). Specifically, Zhao et al. disclose that ribozyme constructs targeted to neuregulin-1 were administered to the developing chick embryos and embryonic ventricle heart tissue development was aborted (see Figure 3) and the nuclei of dying retinal cells was monitored (see discussion at pages 1904 and 1905).

Therefore, Zhao et al. anticipate claims 96-98.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-

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217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg

December 7, 2007

/Terra Cotta Gibbs/